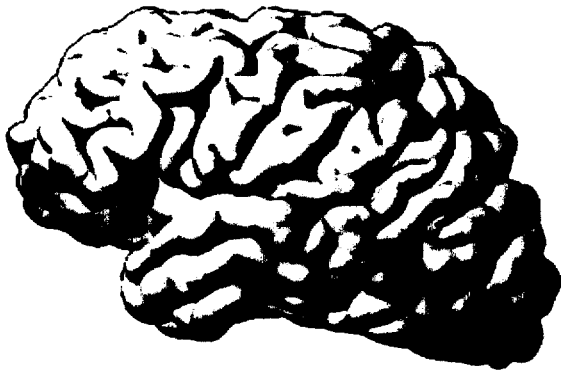
K012563

NOV 0 2 2001



CorTechs
6 Thirteenth Street
Charlestown, MA 02129

Abbreviated 510(k) Summary

Submitter: CorTechs

Address: 6 Thirteenth, Charlestown, MA 02129

Phone number: 617 241-9588

Fax number: 617 241-9620

Contact person: Jeffrey M. Anderson, Ph.D.

Date prepared: August 7, 2001

Device Trade name: Deep Gray

Device Common name: The Deep Gray system

Device Classification name: 21 CFR 892.2050 Picture archiving and communications system.

Product Code: LLZ IMAGE PROCESSING SYSTEM

Classification Panel: Radiology

Substantially Equivalent To:

Vitrea 2, version 2.1
(K002519)
Vital Images, Inc.
3300 Fernbrook Lane North Suite 200
Plymouth, MN 55447

Advantage Windows Tissue Volume Option
(K963345)
General Electric Medical Systems
P.O. Box 414
Milwaukee, WI 53201

Intended use: Deep Gray is intended to measure the volume of any brain structure and tissue from a set of MR images. It provides visualization tools, basic and advanced regions of interest drawing features and volumetric quantification. Deep Gray is to be used by trained physicians.

Device Description: Deep Gray is a software device that provides the following features:

- Import of MR brain images (DICOM 3.0 format).
- Multi-frame and multi-orientation image display.
- Basic regions of interest drawing tools: free hand drawing, filled polygon drawing. Labels can be associated with drawn objects.
- Advanced drawing tool: semi-automatic labeling of normal brain structures and tissues.
- Generation of a report listing the volumes of labeled structures and tissues.

The operator can choose to manually draw and label brain structures and tissues, or they can chose to perform a semi-automatic labeling, followed by visual inspection and manual adjustment. The Deep Gray system does not have any adverse affects on health. This tool measures and displays the volume of regions of interest. The operator can choose to accept, modify, or reject the volume and/or label suggested by the program.

Software Development: The software was designed, developed, tested and validated according to written procedures. These procedures specify individuals within the organization that are responsible for developing and approving product specifications, coding, testing, validation and maintenance.

Performance Testing: Deep Gray has successfully completed integration testing and verification.

Clinical Evaluation: Laboratory performance comparisons between the semi-automatic labeling feature and manual labeling of brain structures has been successfully completed. See attached clinical performance summary for more information.

510(k) Number: None currently exists.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 02 2001

Jeffrey M. Anderson, Ph. D.
Vice President, Research & Development
CorTechs
6 Thirteenth Street
CHARLESTOWN MA 02129

Re: K012563
Trade/Device Name: Deep Gray
The Deep Gray System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving
and Communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: August 7, 2001
Received: August 9, 2001

Dear Dr. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K012563 K012563

Device Name: Deep Gray

NOV 0 2 2001

Indications for Use:

Visualization/Processing/Analysis of brain images from MR scanners.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___✓___ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012563